

Pre-Exposure Prophylaxis for HIV: PrEPing Alaskan Prevention and Care Providers

This webinar will begin shortly.

Webinar Etiquette

- To unmute your phone line
 - Press *7 to unmute.
 - Press *6 to re-mute.
- Verbal Questions
 - There will be dedicated time for questions.
 - Please wait until the Q & A section to ask questions on the phone.
 - Please identify yourself when asking a question or providing a comment.
- Written Questions
 - Participants have the ability to submit written questions during the webinar using the “Chat” function.



Beyond the Basics: The Science of PrEP & US Public Health Service Guidelines

PRESENTED BY:

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DIRECTOR, HIV/STD PREVENTION AND CONTROL, DENVER PUBLIC HEALTH

DIRECTOR, DENVER PREVENTION TRAINING CENTER

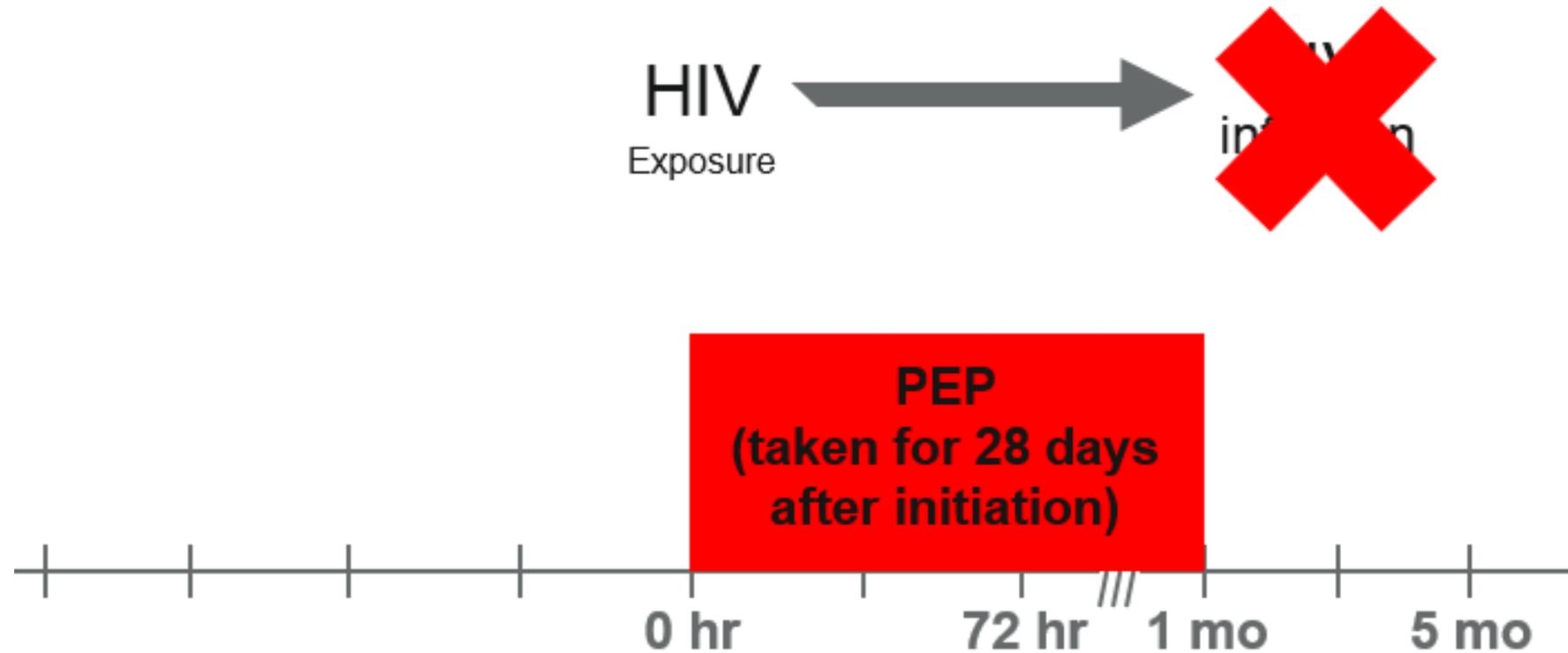
Overview

- What is PrEP
- The Data Leading to PrEP
- PrEP Research
- Key Points Related to PrEP: Adherence, Side effects and Behavioral Counseling
- CDC PrEP Guidelines

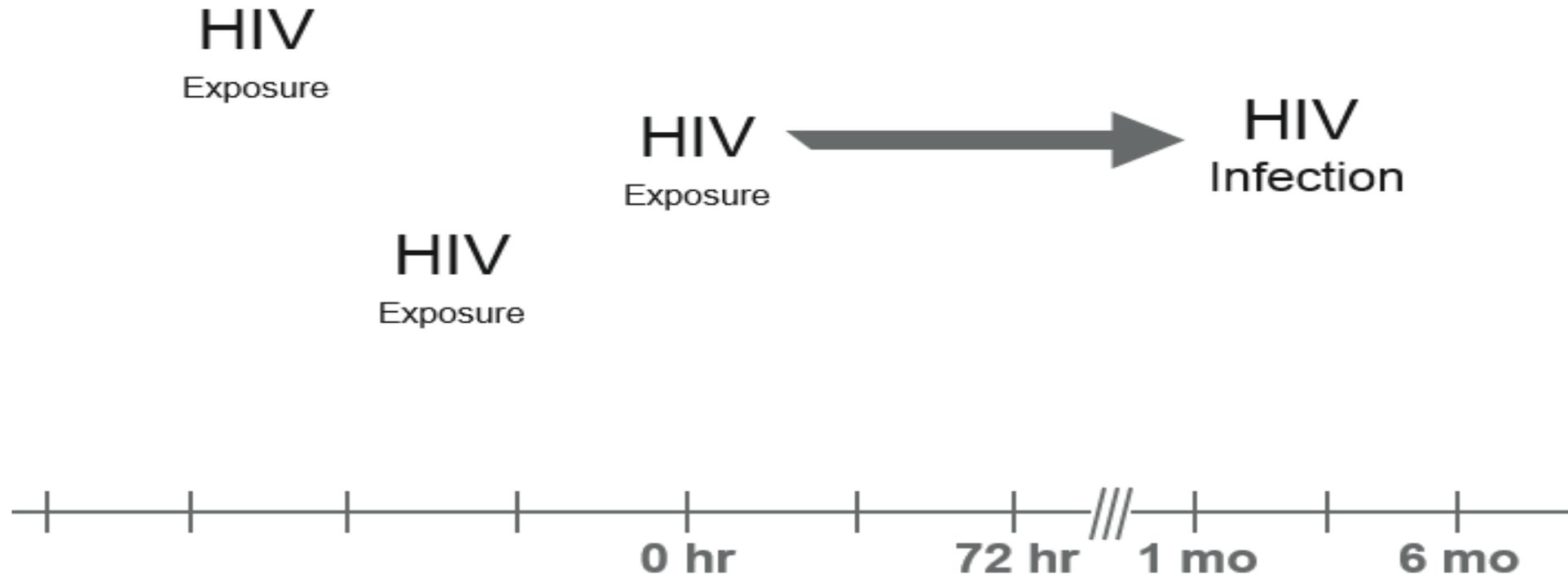
PEP: Isolated HIV Exposure



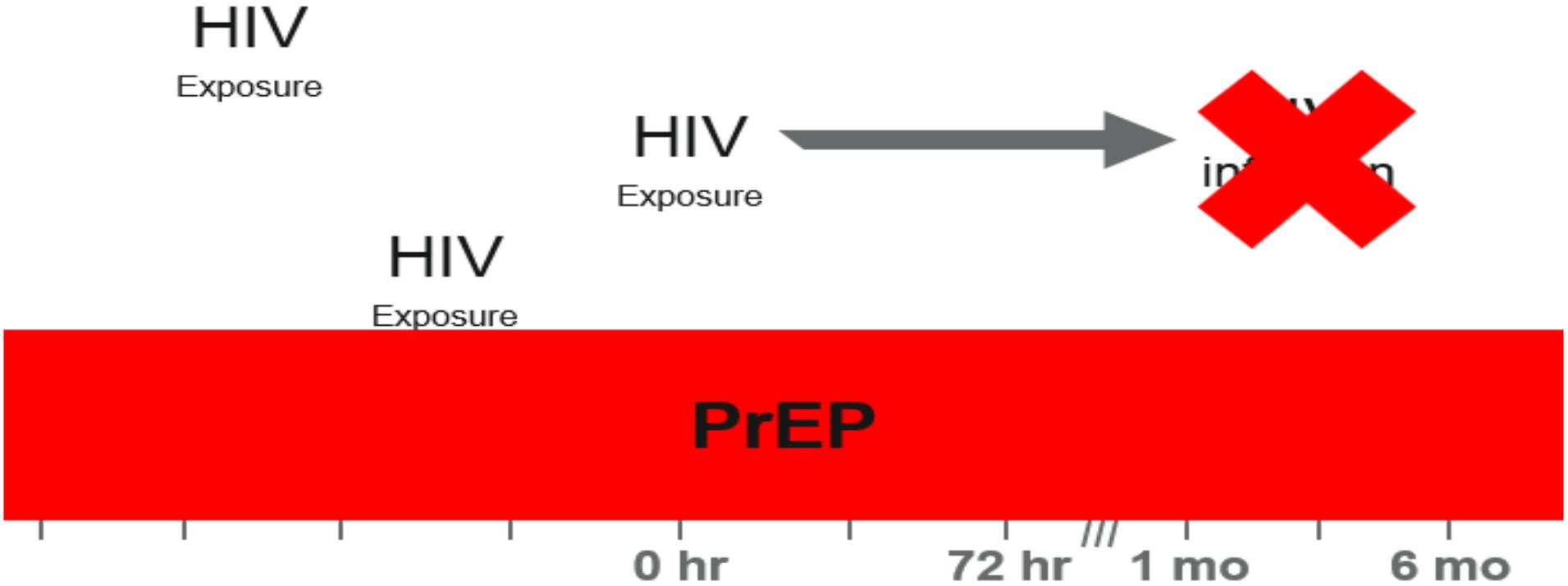
PEP: Prevents Infection After Isolated Exposure



PrEP: Multiple Exposures



PrEP: Prevents Infection Before Exposure



Evolution of HIV Therapies Related to PrEP

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- Highly active antiretroviral therapy (HAART)

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Evolution of HIV Therapies Related to PrEP

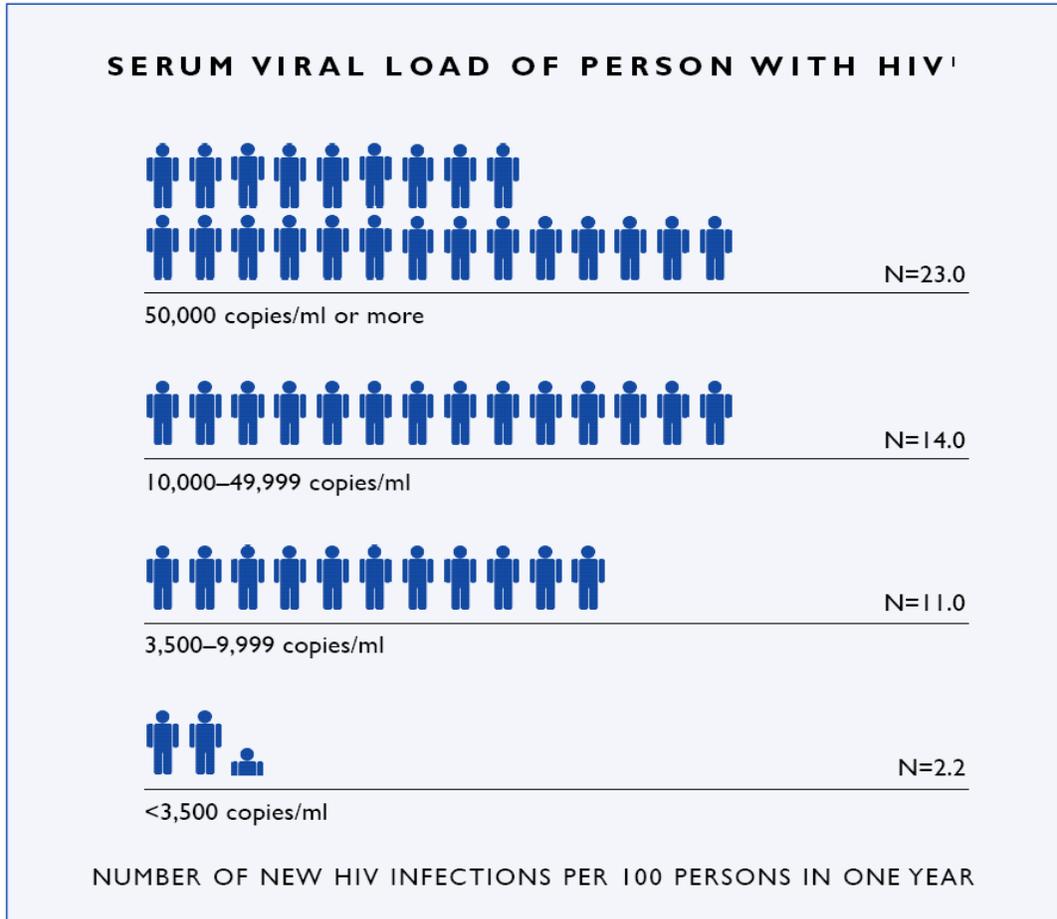
- Highly active antiretroviral therapy (HAART)
- Prevention of mother-to-child transmission (PMTCT)
- Post-exposure prophylaxis (PEP)
- Treatment as prevention (TasP)

Evolution of HIV Therapies Related to PrEP

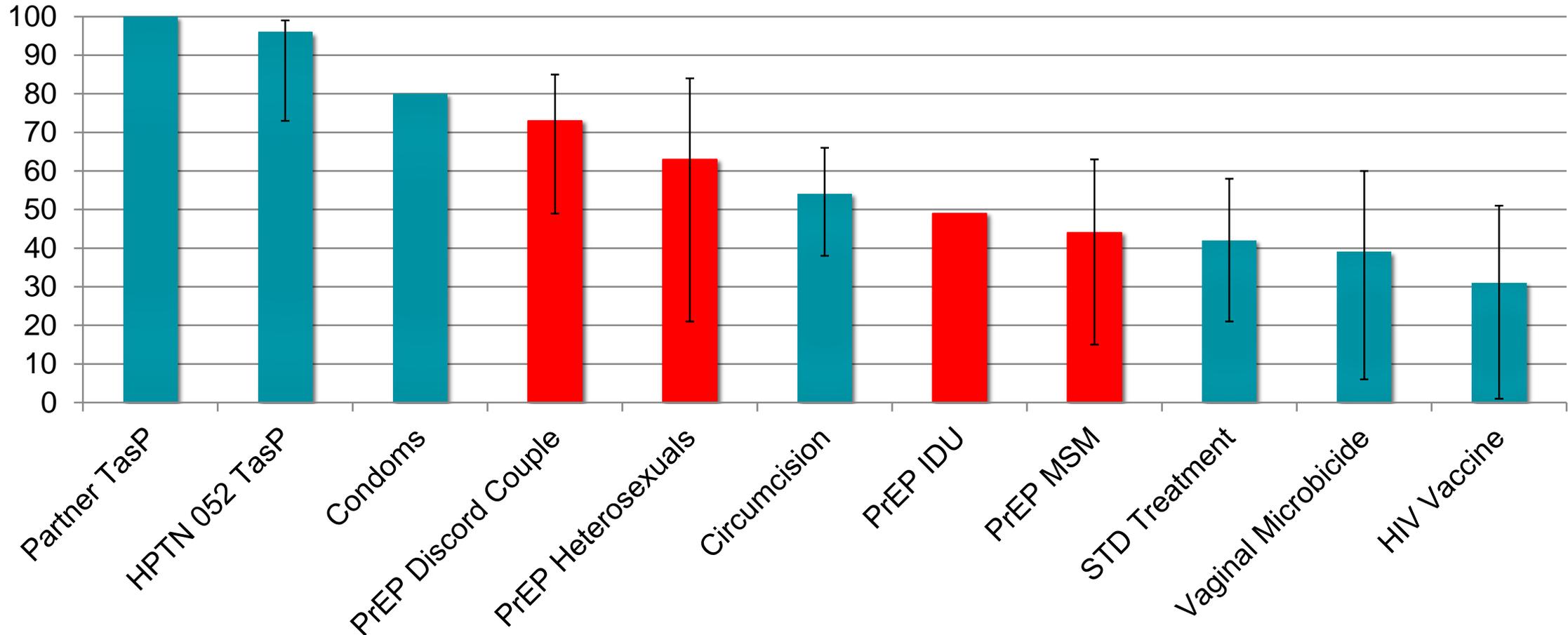
- Highly active antiretroviral therapy (HAART)
- Prevention of mother-to-child transmission (PMTCT)
- Post-exposure prophylaxis (PEP)
- Treatment as prevention (TasP)
- Pre-exposure prophylaxis (PrEP)

Relationship Between HIV Viral Load and HIV Transmission

- HIV viral load is closely associated with HIV transmission
- The lower the viral load, the less likely HIV is to be transmitted



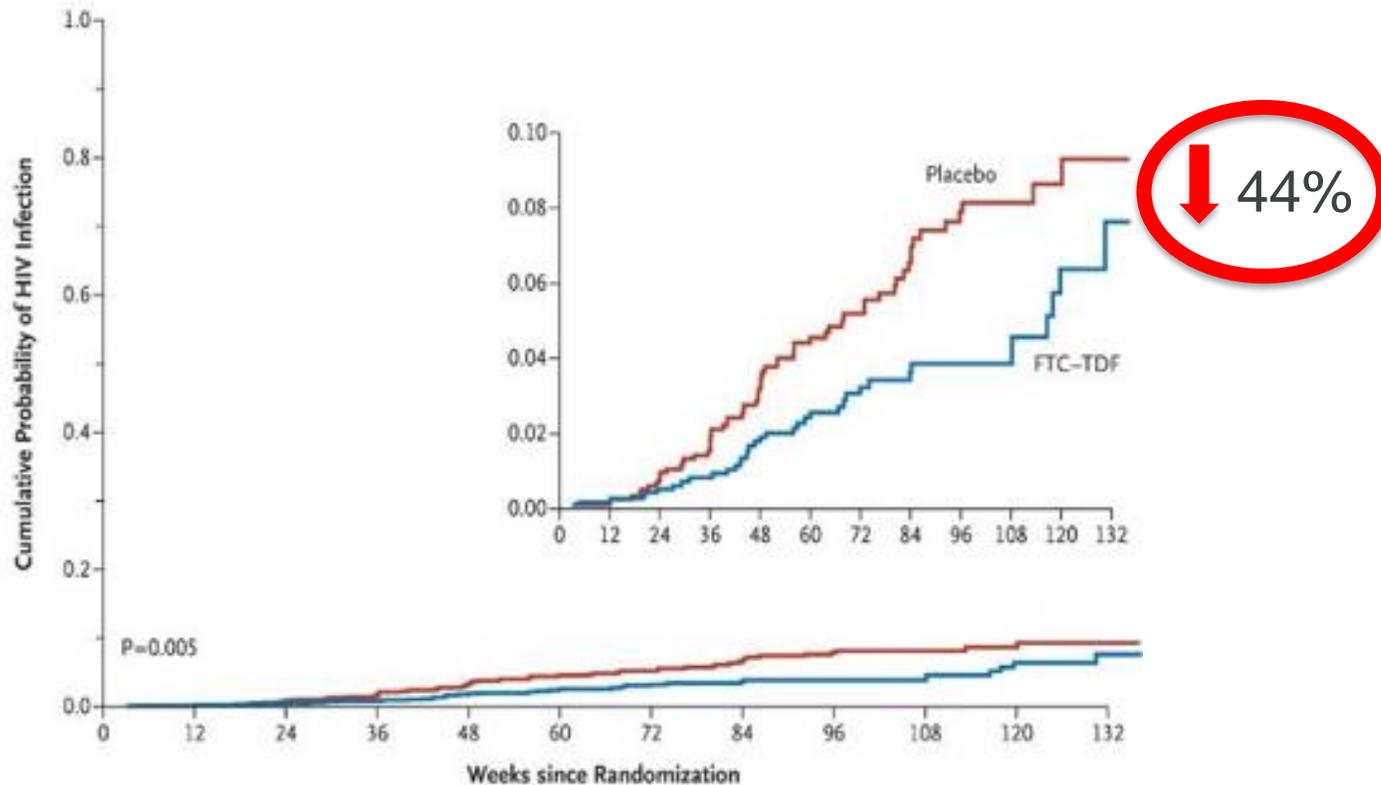
Prevention Science Overview: Biomedical Intervention Efficacy



PrEP

- Treatment before exposure to HIV

iPrEx Study: PrEP in MSM

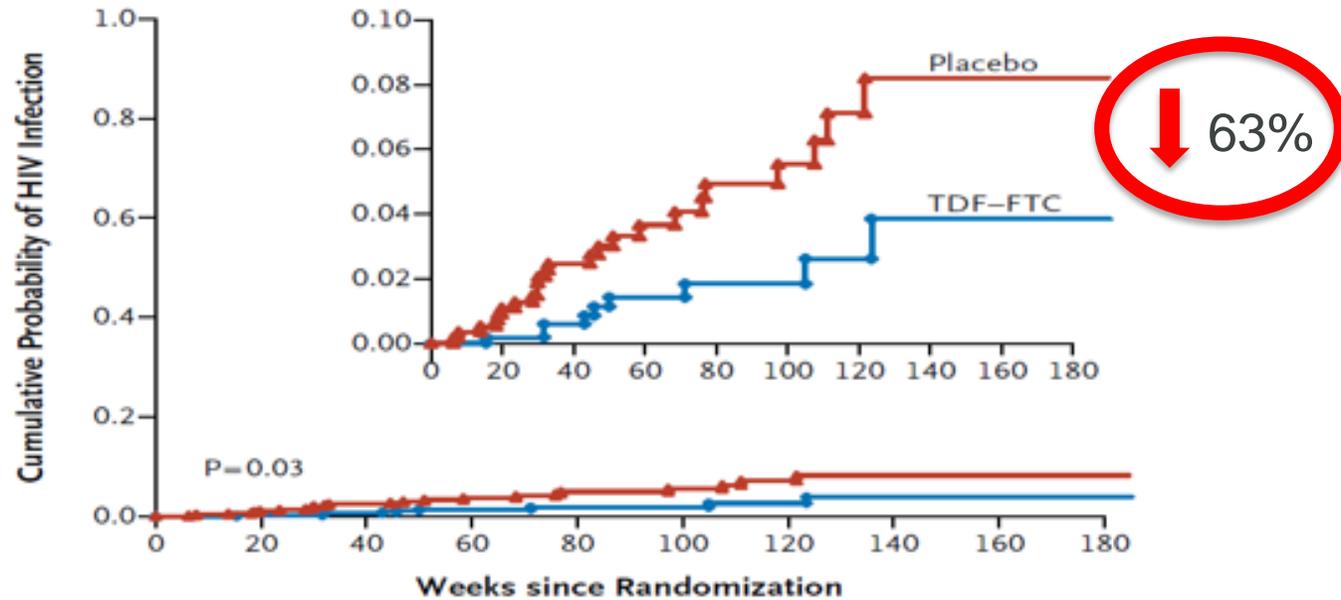


No. at Risk													HIV Infection
Placebo	1248	1194	1108	1005	852	647	546	444	370	258	137	60	64
FTC-TDF	1251	1188	1097	988	848	693	558	447	367	267	147	65	36

Among the men with detectable levels of medicine in their blood (meaning they had taken the pill consistently), PrEP reduced the risk of infection by as much as 92%.

TDF2: Heterosexual PrEP Study

A Modified Intention-to-Treat Analysis



Participants who became infected had far less drug in their blood, compared with matched participants who remained uninfected.

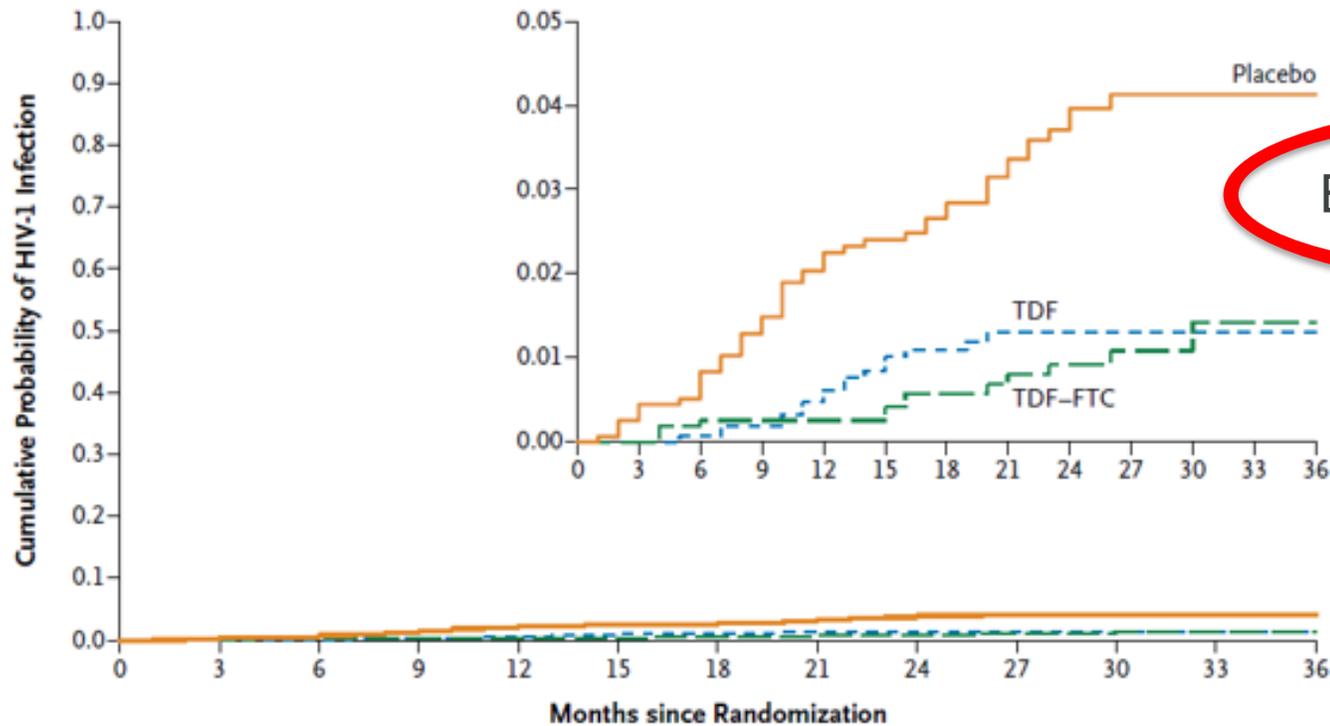
No. at Risk

Placebo	606	529	403	275	208	147	86	44	9	1
TDF-FTC	610	534	406	276	210	142	81	43	7	1

Cumulative No. of HIV Infections

Placebo	0	6	13	17	20	21	23	24	24	24
TDF-FTC	0	1	3	6	7	7	8	9	9	9

Partners PrEP Study: Heterosexual Serodiscordant Couples



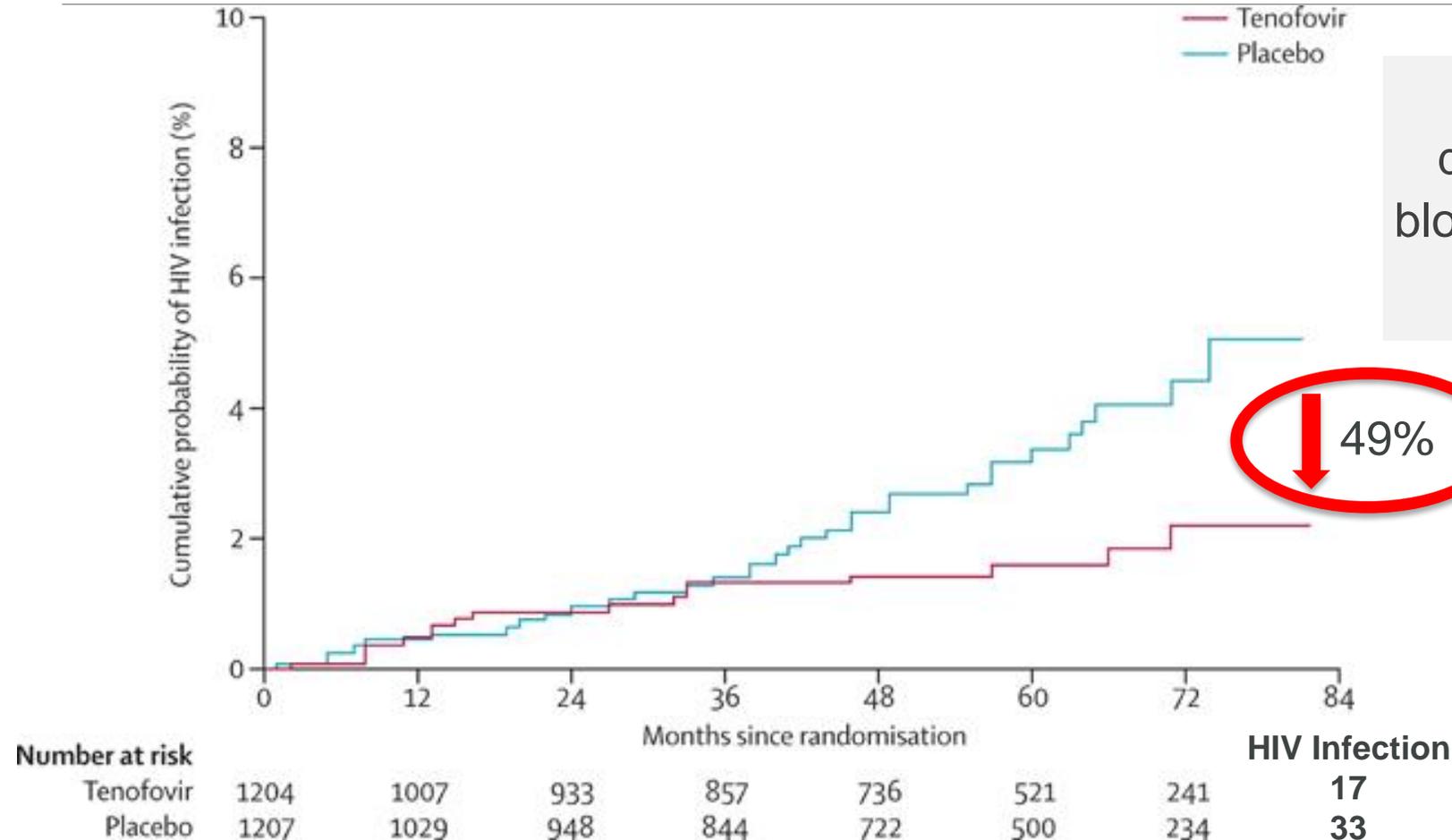
Efficacy: 62 – 73%

Among those with detectable levels of medicine in their blood, PrEP reduced the risk of HIV infection by up to 90%.

No. at Risk	0	3	6	9	12	15	18	21	24	27	30	33	36
TDF	1572	1559	1547	1498	1350	1223	1062	902	735	510	287	108	15
TDF-FTC	1568	1557	1546	1493	1371	1248	1059	901	743	525	291	114	16
Placebo	1568	1557	1544	1487	1347	1224	1061	902	744	523	295	120	18

New Infection
17
13
52

Bangkok Tenofovir Study: PrEP in Injection Drug Users



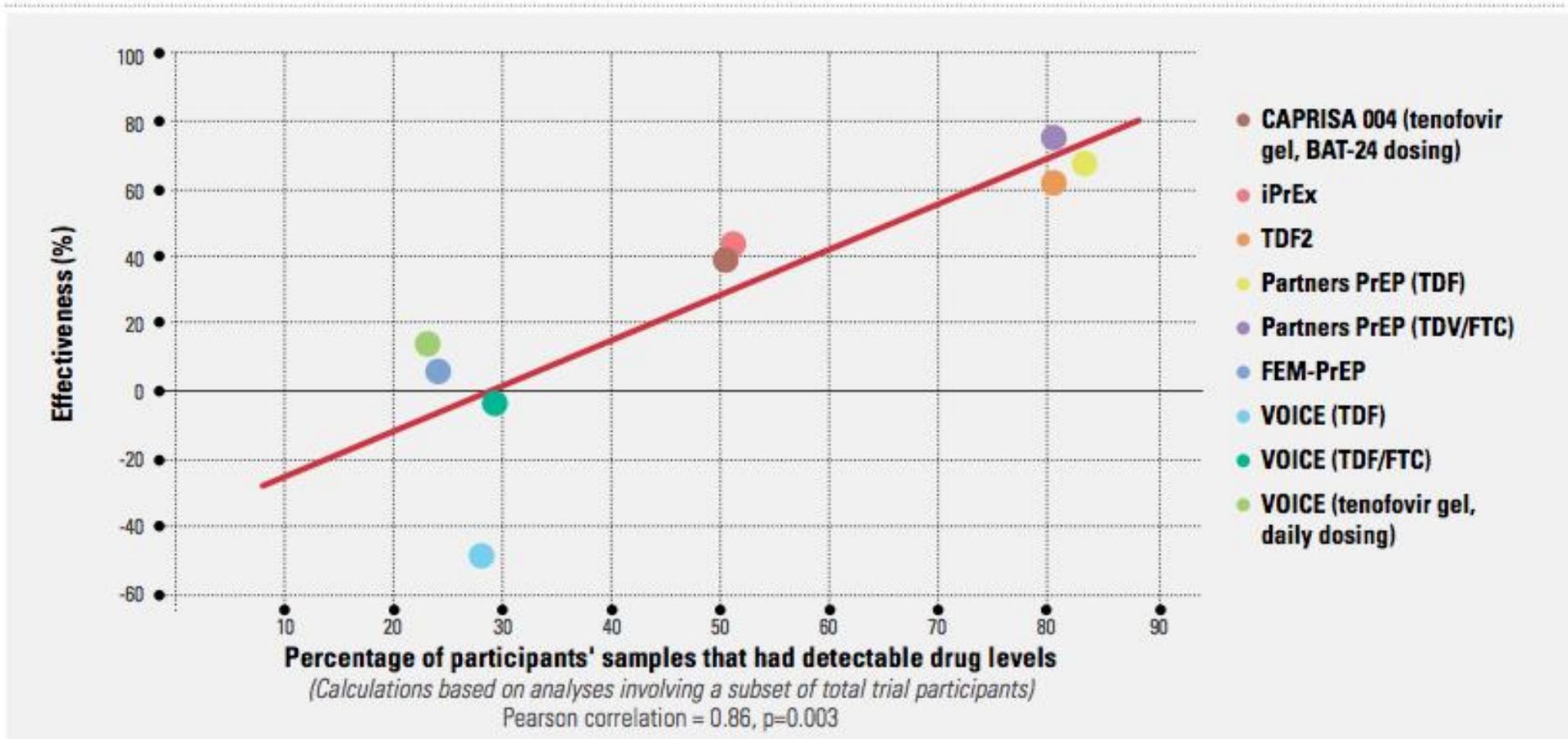
For participants who had detectable tenofovir in their blood, PrEP reduced the risk of infection by 74%

What else have the PrEP studies shown?

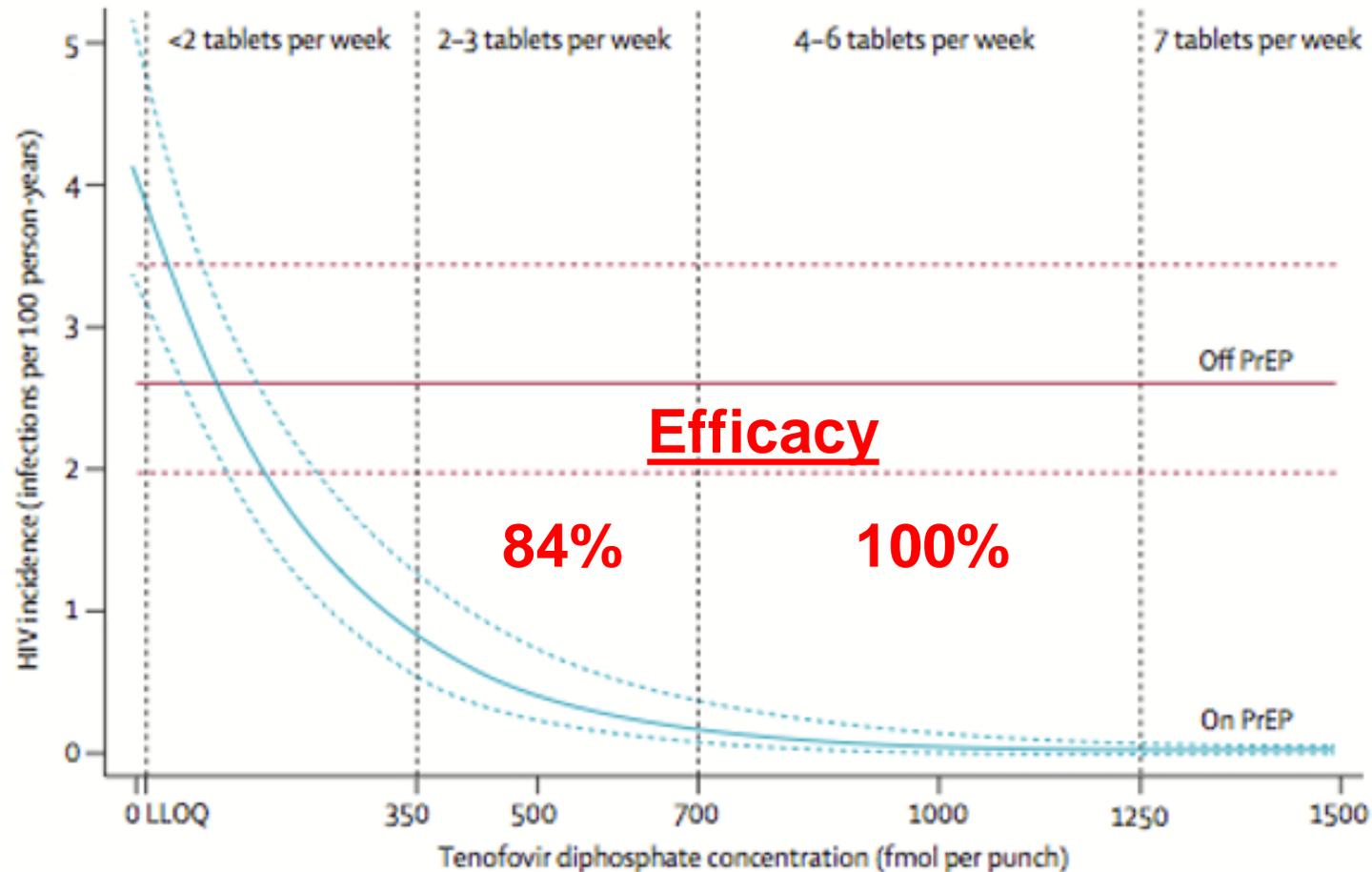
Key points to remember about PrEP:

- Adherence is closely associated with PrEP efficacy
- Though rare, side effects are possible
- Undertake ongoing behavioral risk discussions

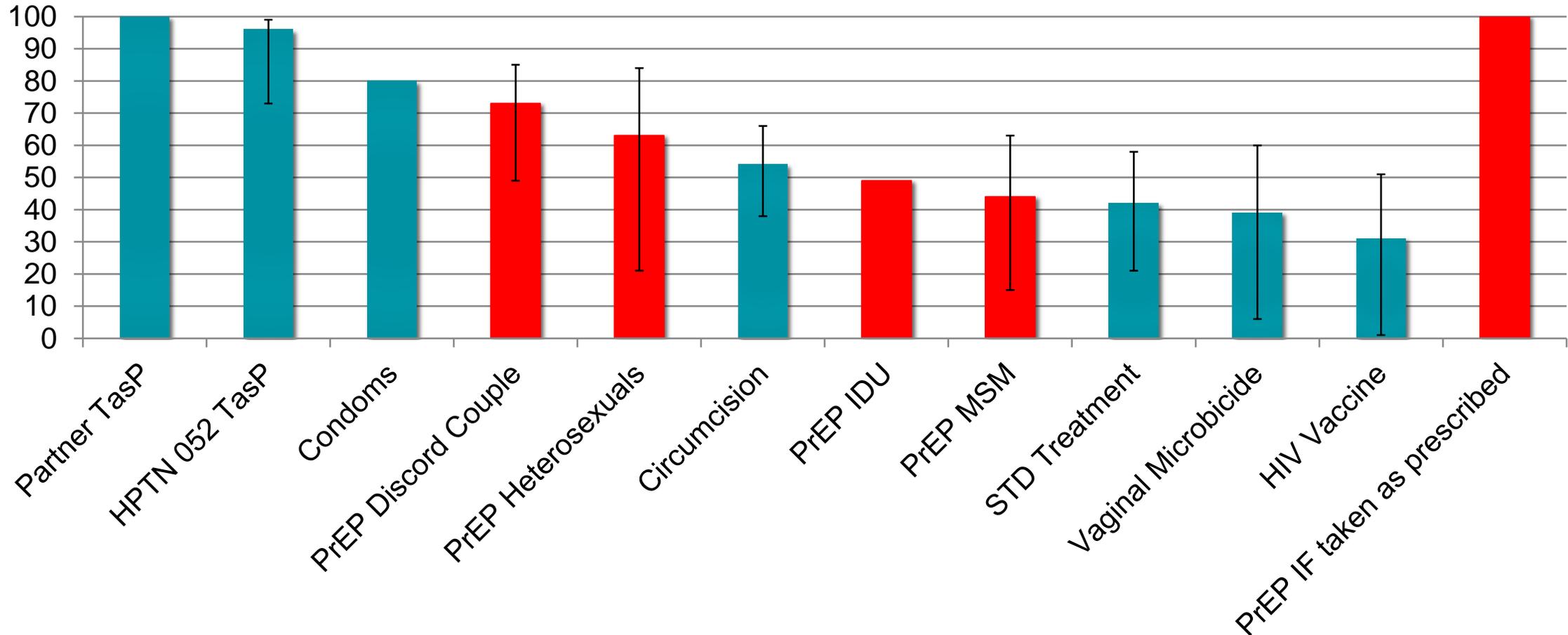
Increased Adherence Associated with Increased Efficacy



Increased Adherence Associated with Increased Efficacy



Prevention Science Overview: Biomedical Intervention Efficacy



Side Effects

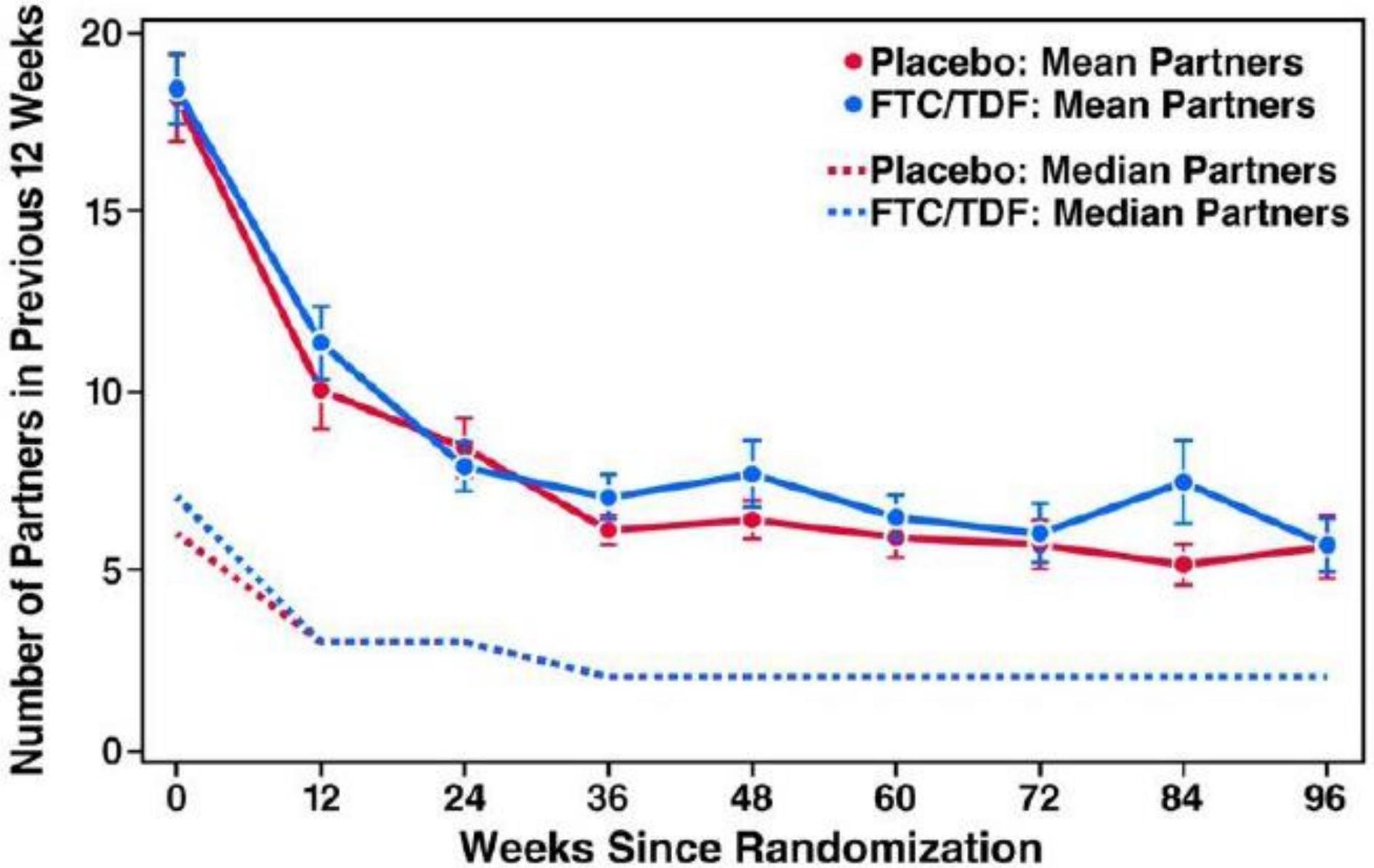
Similar to those seen following years of antiretroviral use in persons living with HIV:

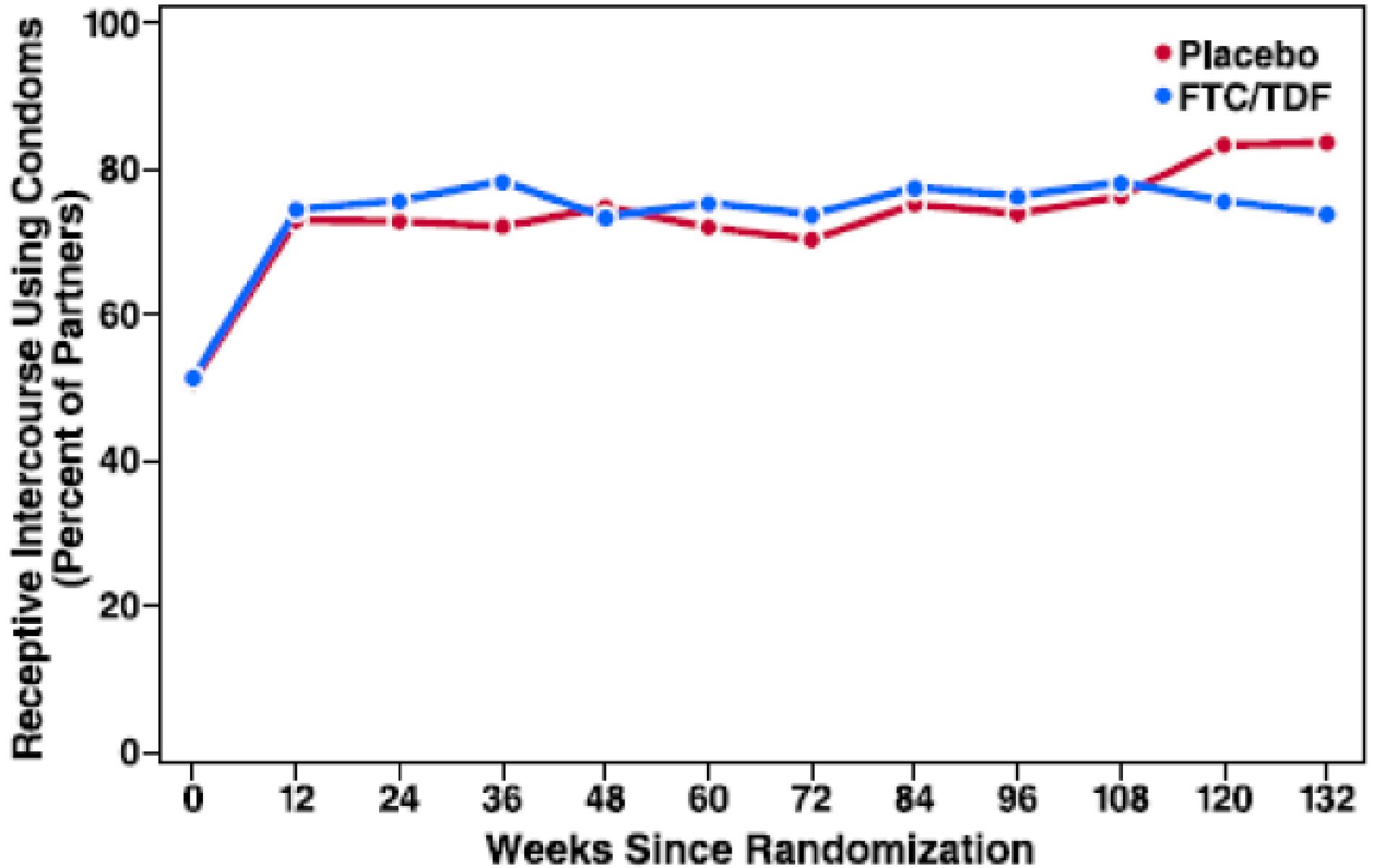
- Diarrhea
- Headache
- Nausea
- Renal dysfunction
- Antiretroviral resistance
- *Bone mineral density loss (has been noted in persons living with HIV, but not yet seen in persons taking PrEP)*

Behavioral Risk Discussions

- PrEP is a biomedical AND a behavioral intervention
- Adherence is closely associated with efficacy
- Behavioral disinhibition – though not seen in the studies – could potentially negate PrEP benefits in real world use settings
- Ongoing risk discussions and risk reduction planning should be an integral component to PrEP

Number of partners actually decreased





Condom use increased

Federal PrEP Guidelines

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES - 2014

A CLINICAL PRACTICE GUIDELINE



Summary of Guidance for PrEP Use

	Men Who Have Sex With Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection:	<ul style="list-style-type: none"> Sexual partner with HIV Recent bacterial STD High number of sex partners History of inconsistent or no condom use Commercial sex work 	<ul style="list-style-type: none"> Sexual partner with HIV Recent bacterial STD High number of sex partners History of inconsistent or no condom use Commercial sex work Lives in high-prevalence area or network 	<ul style="list-style-type: none"> HIV-positive injecting partner Sharing injection equipment Recent drug treatment (but currently injecting)
Clinically eligible:	<ul style="list-style-type: none"> Documented negative HIV test before prescribing PrEP No signs/symptoms of acute HIV infection Normal renal function, no contraindicated medications Documented hepatitis B virus infection and vaccination status 		
Prescription	Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90 day supply		
Other services:	<ul style="list-style-type: none"> Follow-up visits at least every 3 months to provide: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STD symptom assessment At 3 months and every 6 months after, assess renal function Every 6 months test for bacterial STDs 		
	<ul style="list-style-type: none"> Do oral/rectal STD testing 	<ul style="list-style-type: none"> Assess pregnancy intent Pregnancy test every 3 months 	<ul style="list-style-type: none"> Access to clean needles/syringes and drug treatment services

Source: US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States —2014: a clinical practice guideline.

PrEP

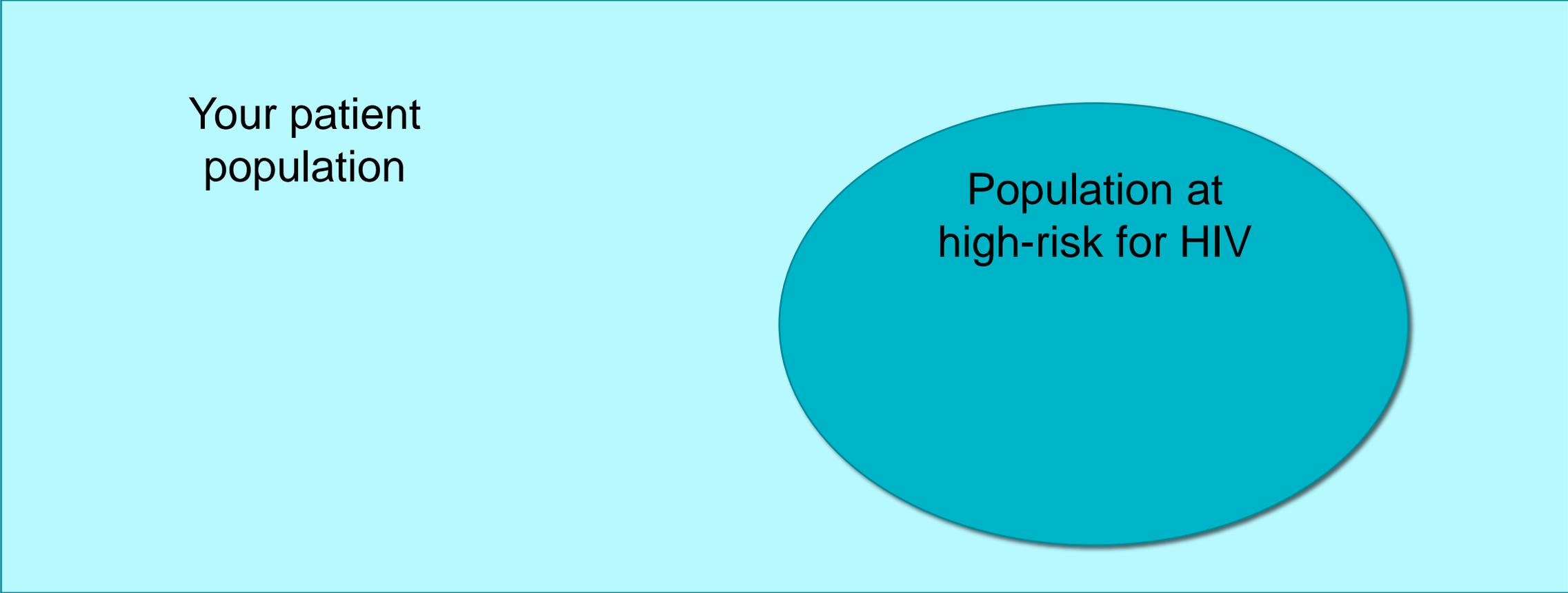
- Identifying persons at risk for HIV who might benefit from PrEP

Population versus Individual Risk

Your patient
population

Population versus Individual Risk

Your patient
population



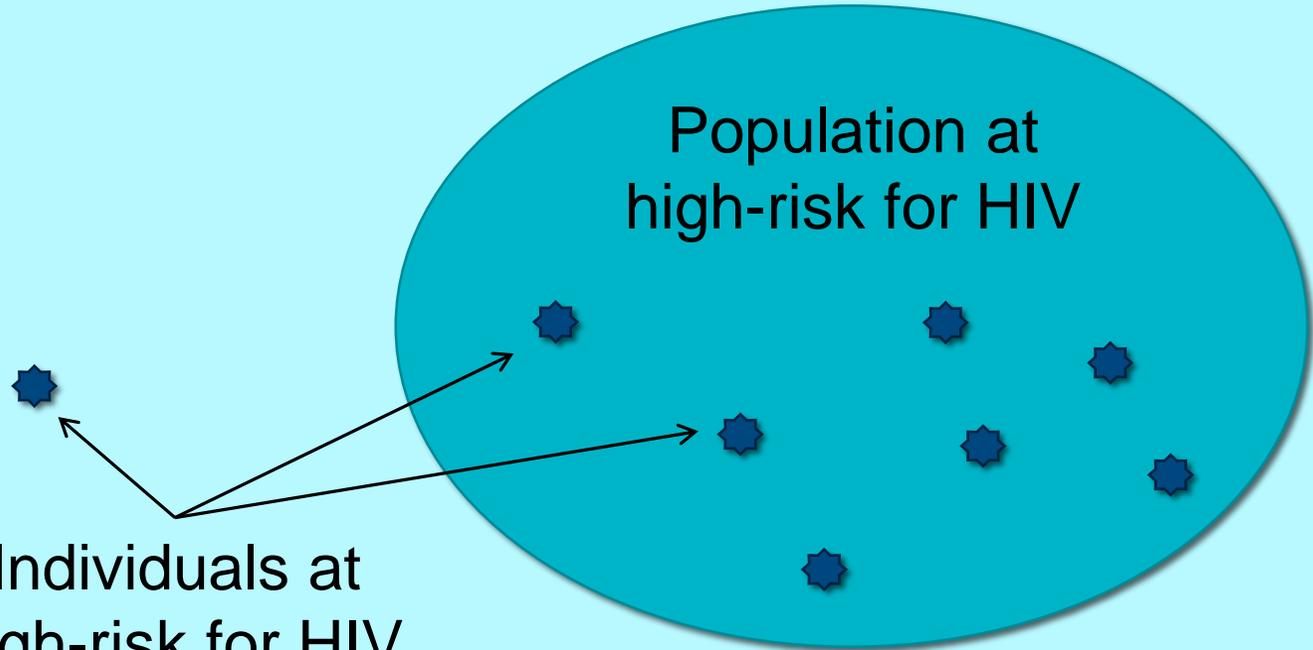
Population at
high-risk for HIV

Population versus Individual Risk

Your patient
population

Population at
high-risk for HIV

Individuals at
high-risk for HIV

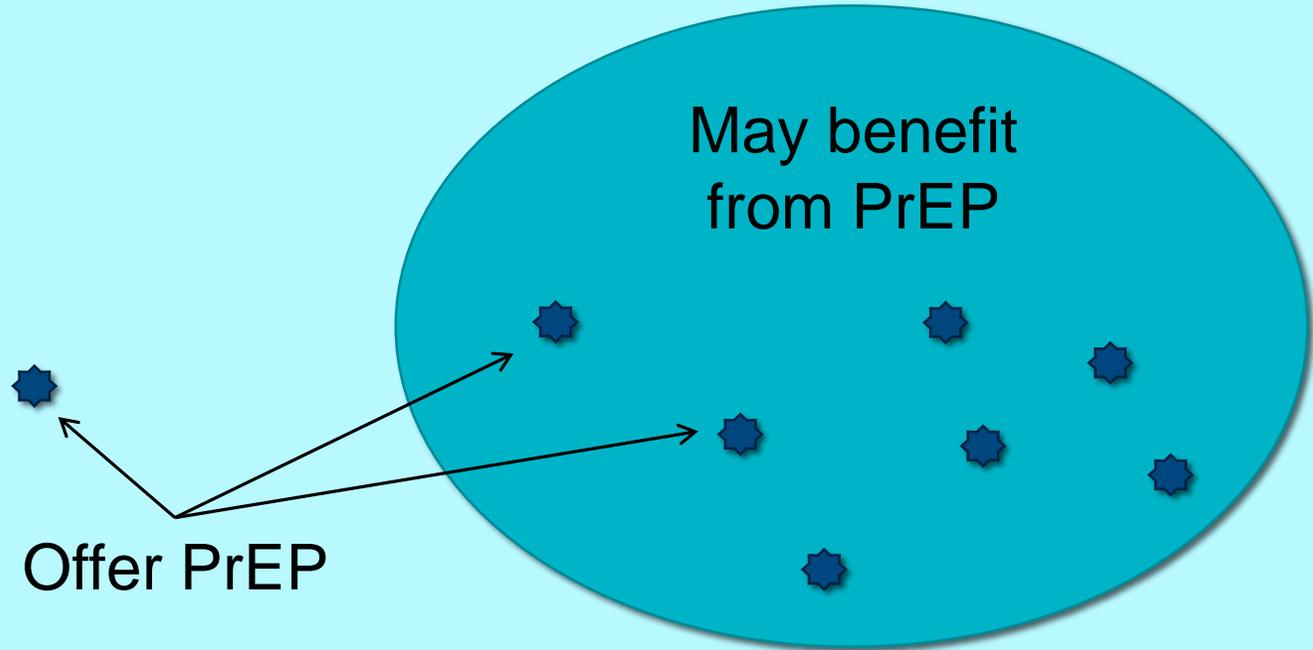


Pulling it all together

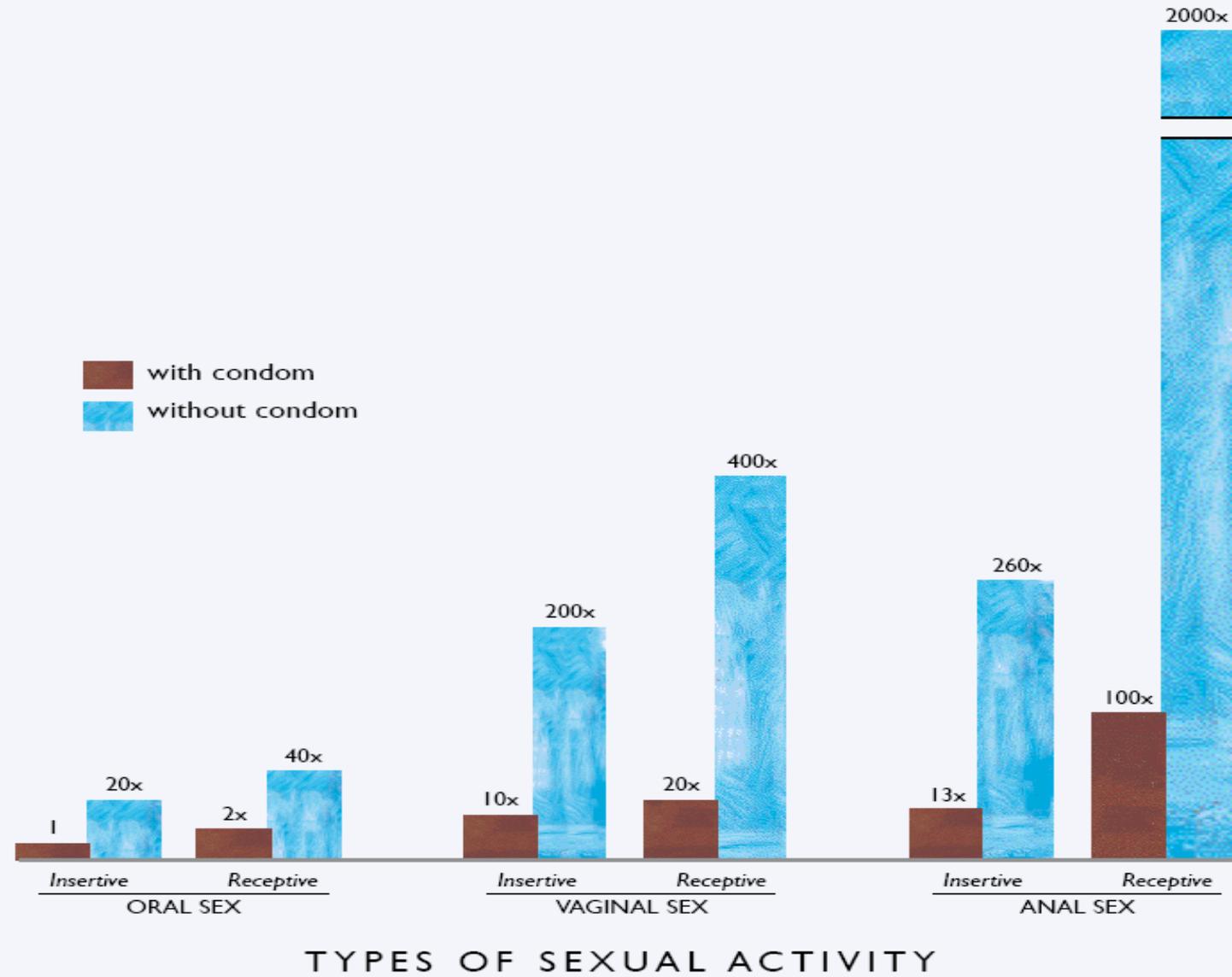
No need for PrEP

May benefit from PrEP

Offer PrEP



RELATIVE RISK FOR TRANSMISSION¹



Online Risk Calculator

- A decision-analytic model of PrEP for MSM.
- Tool available online at: <https://ictrweb.johnshopkins.edu/ictr/utility/prep.cfm>.
- Population Cost-Effectiveness Calculator also developed and available at same web address.

HIV Pre-Exposure Prophylaxis (PrEP) Risk Assessment Tool: Individual Risk Calculator

1. What percent of the time do you use condoms when having anal sex, including both receptive (bottom) and insertive (top)?  %

2. What percent of the time are you the insertive partner (top) when having anal sex?  %

3. On average, how many times per month do you have anal sex? 

4. Are you in a monogamous relationship with an HIV positive partner? Yes No

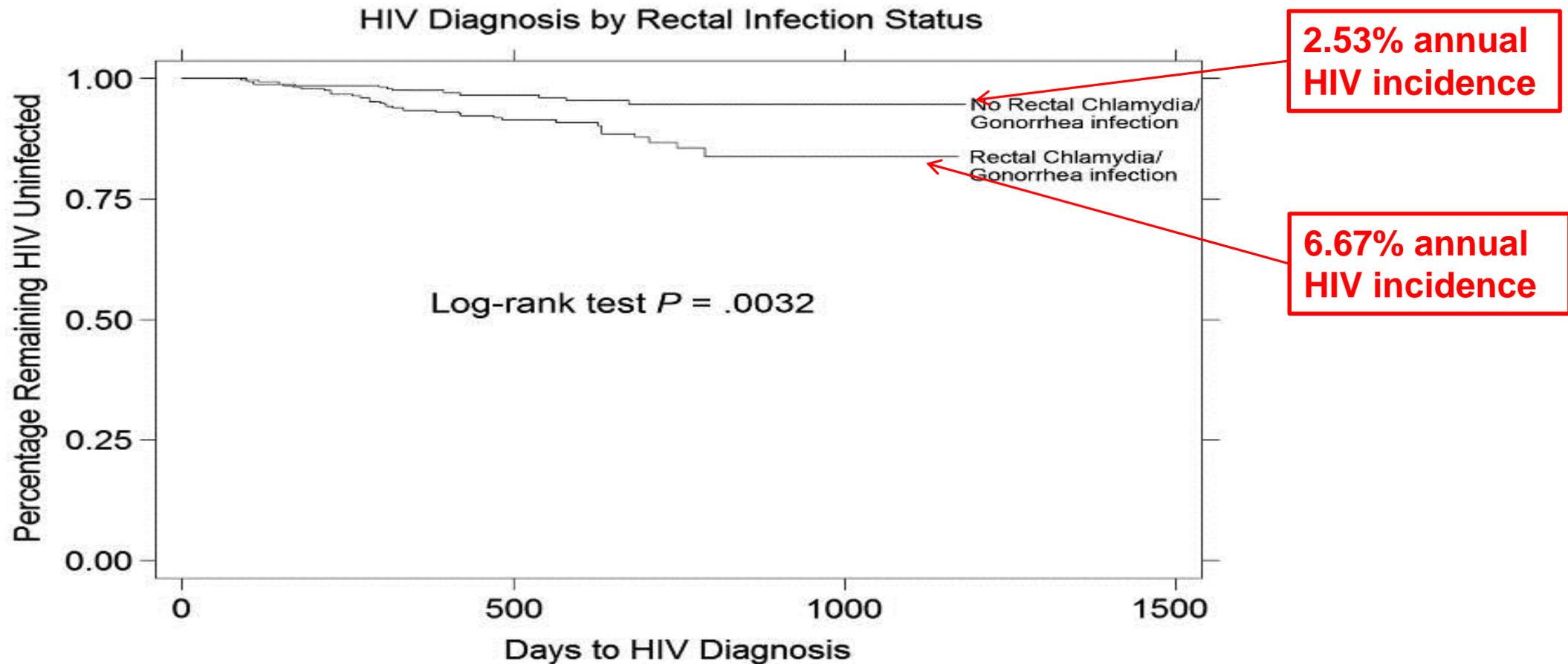
HIV Pre-Exposure Prophylaxis (PrEP) Risk Assessment Tool: Individual Risk Calculator

1. What percent of the time do you use condoms when having anal sex, including both receptive (bottom) and insertive (top)? 50 %
2. What percent of the time are you the insertive partner (top) when having anal sex? 50 %
3. On average, how many times per month do you have anal sex? 6
4. Are you in a monogamous relationship with an HIV positive partner? Yes No
- 4b. What is the HIV prevalence in your community?
(click [here](#) for CDC estimates of HIV prevalence among MSM by metropolitan area, age, and race/ethnicity. If left blank, the national average of 19% will be used) 16 %

Risk of acquiring HIV this year:

Without PrEP	1 in 44 (2.3%)
PrEP, expected adherence ¹	1 in 77 (1.3%)
PrEP, expected adherence + increase in risky behavior ²	1 in 59 (1.7%)
PrEP, high adherence ³	1 in 538 (0.2%)
PrEP, high adherence and 100% condom use	1 in 1614 (0.1%)

Ask about STDs: HIV Incidence Increased Following Rectal Bacterial Infections in MSM



Ask about STDs: HIV Incidence Increased in MSM with Prior Syphilis

- Results from the iPrEx study of PrEP in MSM:
 - 2.8 cases of HIV per 100 person-years follow up for those with ***no incident syphilis***
 - 8.0 cases of HIV per 100 person-years follow up for those with ***incident syphilis***
- Hazard ratio of 2.6 for acquiring HIV for those with syphilis

Syphilis is up

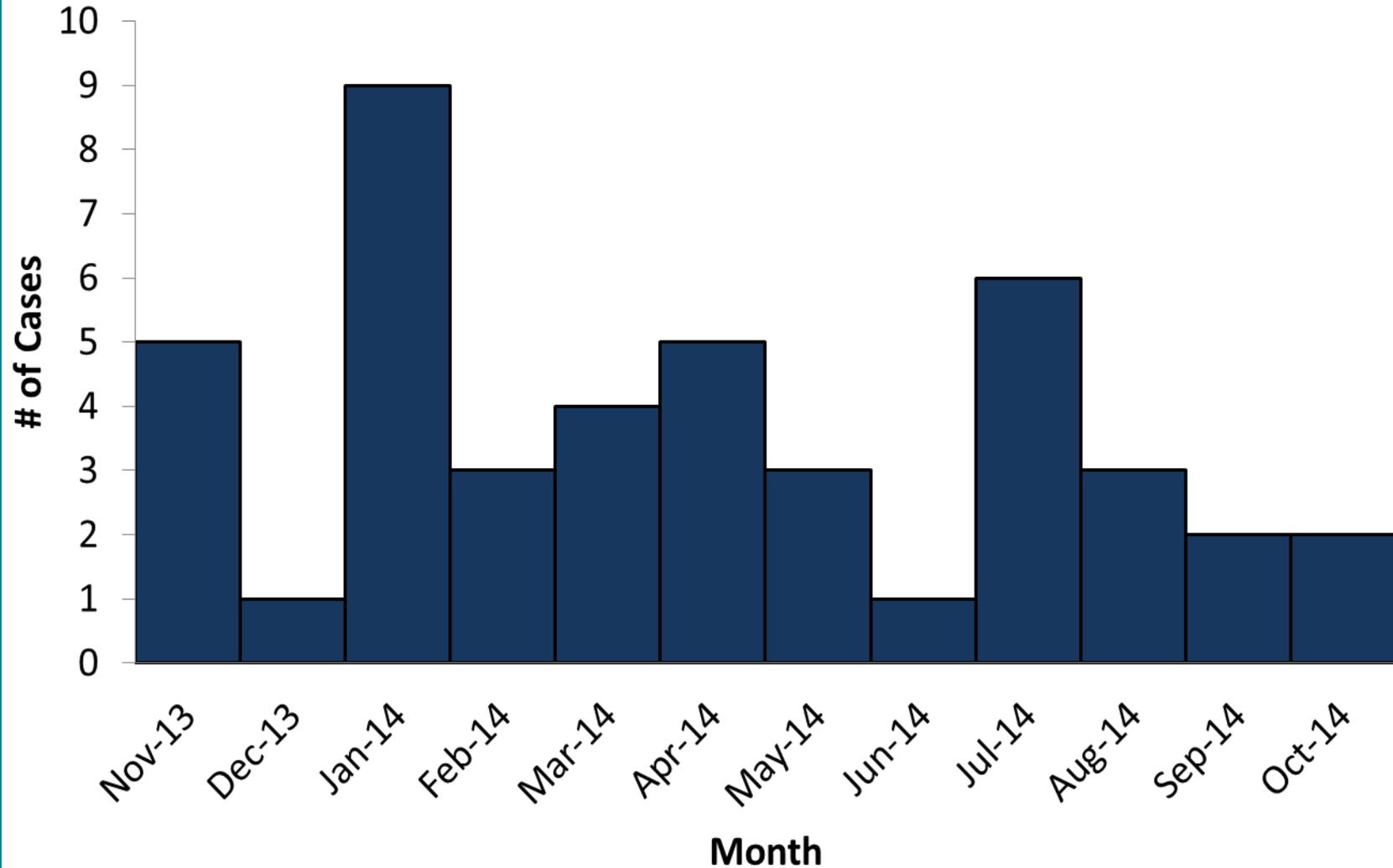
2012 = 19 cases

2013 = 31 cases

2014 = 39 cases (10/31)

72% in MSM

Cases of Newly Diagnosed Syphilis— Alaska, November 2013 – October 2014



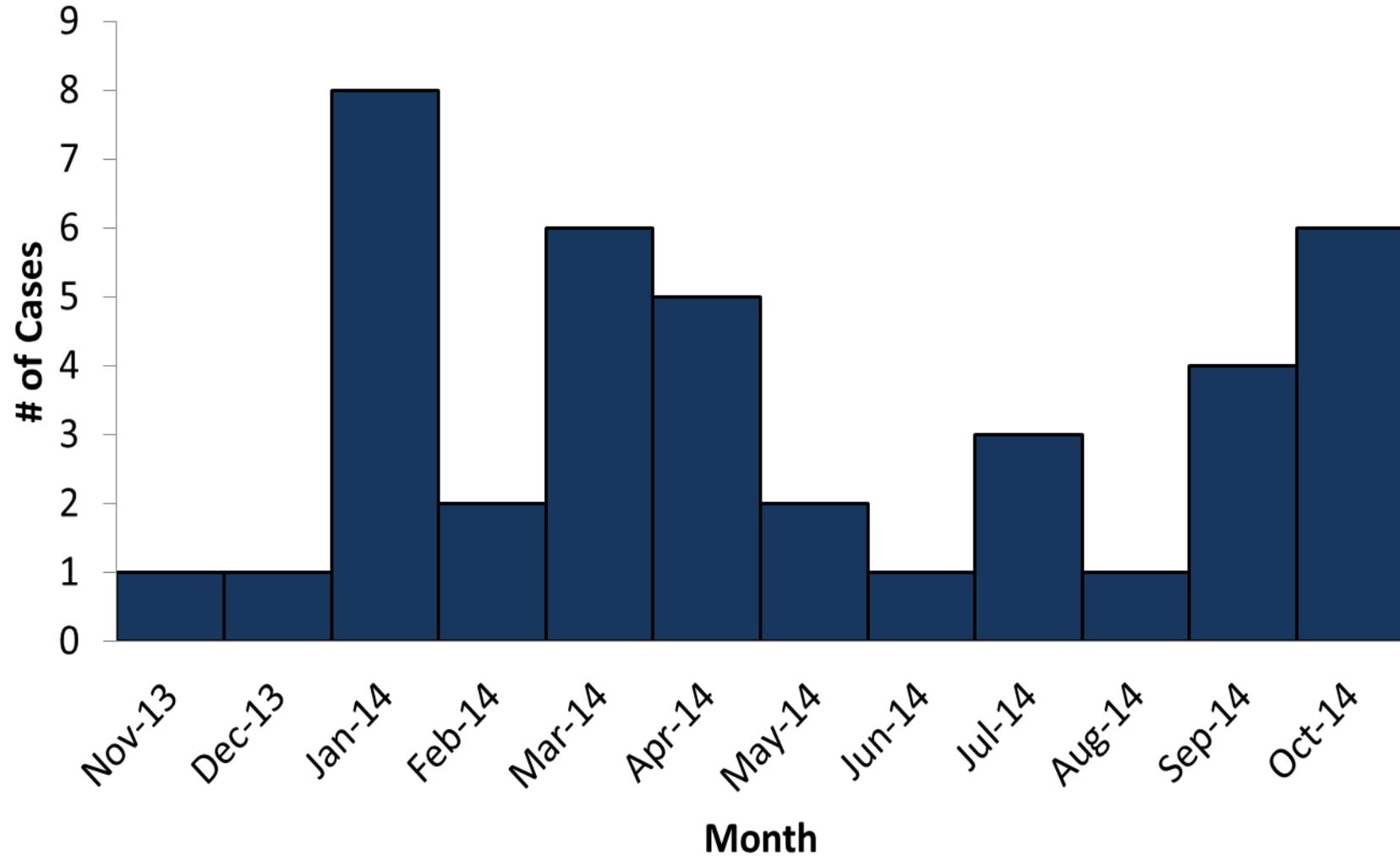
HIV is up

2013 = 24 cases

2014 = 38 cases (10/31)

58% in MSM

Cases of Newly Diagnosed HIV — Alaska, November 2013 – October 2014



Prescribing PrEP

- Rule out chronic and acute HIV infection
- Rule out renal insufficiency
- Screen for STDs
- Screen for Hepatitis

Prescribing PrEP

Prescribe up to 3 months worth of PrEP

- The only regimen approved by the FDA and recommended for PrEP with all populations specified in the guideline is the co-formulated tenofovir 300 mg/entircitibine 200 mg (Truvada). (IA)
- Tenofovir alone has shown efficacy and safety in heterosexuals and IDU (but not MSM) and can be considered for these populations. (IC)
- The use of other medications in place or in addition to TDF/FTC or TDF alone is not recommended. (IIIA)
- Prescribing PrEP for coitally-timed or other noncontinuous daily use is not recommended. (IIIA)

Reinforcing Adherence

Adherence counseling

- Establish trust and bidirectional communication
- Provide simple explanations and education
- Support adherence
- Monitor medication adherence in a nonjudgmental manner

Reinforcing Safe Behaviors

Behavioral risk-reduction counseling

- Establish trust and bidirectional communication
- Provide feedback on HIV risk factors identified during sexual and substance use history taking
- Support risk reduction efforts
- Monitor behavioral adherence in a nonjudgmental manner

Follow-up Visits

Every 3 months

- Repeat HIV testing and assess for signs/symptoms of acute infection to document that patients are still HIV-negative. (IA)
- Repeat pregnancy testing for women who may become pregnant.
- Provide a prescription or refill authorization of daily TDF/FTC for no more than 90 days (until the next HIV test).
- Assess side effects, adherence, and HIV risk behaviors.
- Provide support for medication adherence and risk-reduction behaviors.
- Respond to new questions and provide any new information about PrEP use.

Follow-up Visits

Every 6 months

- Monitor creatinine clearance. (IIIA)
- Conduct STI testing recommended for sexually active adolescents and adults (i.e. syphilis, gonorrhea, chlamydia).

Follow-up Visits

Discontinuing PrEP

- Document HIV status
- Understand reason for discontinuing PrEP
- Counsel based on recent adherence and risk behaviors

Clinical Provider's Supplement

US PUBLIC HEALTH SERVICE

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2014

CLINICAL PROVIDERS' SUPPLEMENT



NACCHO's Webcast Series on PrEP and Local Health Departments

Module 1

- PrEP for HIV Prevention: An Introduction
- **Beyond the Basics: The Science of PrEP**
- **US Public Health Service Clinical Practice Guidelines for PrEP**

Module 2

- Who Might Benefit from PrEP: Population-level Risk Assessments
- Who Might Benefit from PrEP: Individual-level Risk Assessments

Module 3

- Increasing PrEP Awareness and Knowledge in Your Jurisdiction
- Incorporating PrEP into Comprehensive HIV Prevention Programs

PrEP Poses Many Questions

After watching the webcasts in Modules 1 and 2,
join us for a live webinar discussion on

Friday, November 21, 2014

from 1:00-2:00 PM ET.

Register at <http://www.naccho.org/topics/HPDP/hivsti/prep.cfm>

The webinar will be archived and made available via naccho.org.

DenverPTC.org



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• Monday - Friday | 7 AM - 5 PM MT | 8 AM - 6 PM CT •



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NORTHWEST AIDS EDUCATION AND TRAINING CENTER



Alaska Native Tribal Health Consortium HIV/AIDS Clinical Services

HRSA Ryan White Part C Early Intervention Services
Northwest AIDS Education and Training Center-Alaska
State of Alaska CDC/Prevention

State of Alaska PrEP Webinar
11/20/2014



What Do We Do?

- **Clinical Care**
 - ANTHC
 - ICHC Fairbanks
- **Collaboration/Co-management**
- **Intensive Case Management**
- **Consultation**
 - Northwest AIDS Education and Training Center (NWAETC) Local Performance site

Ryan White Part C NWAETC

Available for treatment, case
management and medical
consultation for providers caring for
all HIV+ Alaskans

(907) 729-2907

(888) 855-8006 #2

NWAETC

Future Trainings?

Northwest AIDS Education and Training
Center, Alaska Local Performance Site

Training coordinator: Joe Cantil

(907) 729-3956

- ANTHC HIV Clinical Team

- Beth Saltonstall, MD

- Medical director

- Terri Bramel, PA-C

- Clinical Specialist

Patient Care Managers:

- Lisa Rea, RN

- Julie Witmer, RN

- SCF- Thor Brendtro, RN

- (907) 729-4209

ANMC resources

- Infectious Disease Specialists

- Jake Gray, MD
- Ben Westley, MD
- Cliff Schneider, MD

Call ANMC and ask for ID consult on call

(907) 563-2662

Community Resources

Ben Westley, MD
Infectious Disease
(907) 563-3929

Rod Gordon, PharmD
Greatland Infusion Pharmacy
(907) 561-2421

State of Alaska Epi

Melissa Boyette

HIV Surveillance and Disease Intervention

269-8057

Jessica Harvill

HIV Prevention

269-5221



800 478-2437
263-2050

*Serving all Alaska
except Fairbanks
region. Anchorage and
Juneau offices*

RW Part B funding
Medical case management
Housing assistance
Statewide ADAP Provider
Rapid HIV and HCV Testing
Syringe exchange

Web-based Sexual Health Education

The screenshot shows the homepage of **iknowmine.org**. At the top left is the logo. Navigation tabs include "FOR PARENTS", "FOR PROVIDERS", and a search bar. A menu bar lists "Sexual Health", "LGBT", "Relationships", "Your Body", "Your Emotions", and "Other Resources". A prominent banner for "National NATIVE HIV/AIDS Awareness Day" on "March 20th" at the "Alaska Native Medical Center Hospital Lobby 10am - 2pm" is displayed. To the right of the banner is a list of services: "order condoms", "order testing kit", "find a clinic", "txt yr questions", "other cool stuff", and "FAQ". A yellow vertical button labeled "ask a question" is on the right side. Below the banner are several smaller boxes: a tweet, a "Get a Free STD Test" offer with the "Spawr Safety" logo, and a quote: "We are responsible for each other and ourselves - Kodiak Alutiq Traditional Value". A "Welcome to iknowmine.org" section follows, explaining the mission and listing topics like "STDs, pregnancy, nutrition, Am I Gay?, dating violence". To the right of this section is a "we are social" sidebar with links for Facebook, Twitter, Tumblr, YouTube, and a mailing list. At the bottom, there is a "Share this page:" section with icons for Facebook, Twitter, Tumblr, and Email, and a "HIV/AIDS" section.



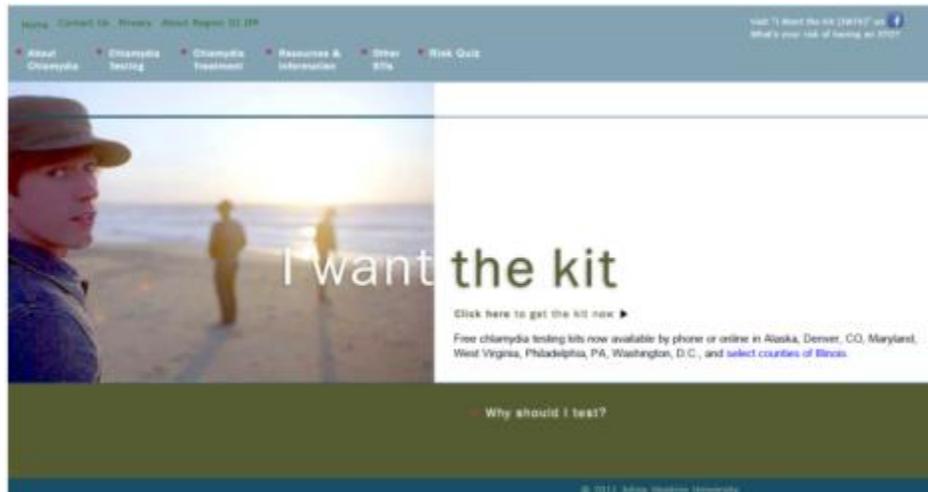


On the Web:

www.iwantthekit.org



Female Testing Kit Contents



Male Testing Kit Contents



Questions

- Verbal Questions
 - Press *7 to unmute
 - Press *6 to re-mute
 - Please identify yourself
- Written Questions
 - Submit using chat
- If you have questions regarding this webinar, please contact Jillian Casey at jcasey@NASTAD.org